



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,344	01/09/2001	Pierre Jean Francois Layrolle	04148-00005	8849

7590 05/06/2003

John P. Iwanicki
BANNER & WITCOFF, LTD.
28th Floor
28 State Street
Boston, MA 02109

EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/757,344	LAYROLLE ET AL.
Examiner	Art Unit	
Jennifer Kolb Michener	1762	

-- Th **MAILING DATE** of this communication app ars on the cov r she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 27-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 27-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 27-33 and 36-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Leitao.

Regarding independent claims and claim 32, Leitao teaches a method for producing an implant article. Leitao teaches coating the implant with an amorphous calcium phosphate layer, which can be made from a combination of calcium and phosphate ions together with hydroxide, magnesium, and/or chloride ions, among others (col. 2, lines 20-25). The calcium phosphate layer may also form hydroxyapatite (col. 5, line 13). In specific regard to claim 36, Leitao teaches pre-coating with the above coating material and then placing the implant into the body where an additional calcium phosphate layer is formed on the implant *in vivo* (col. 3, lines 1-6).

Because Leitao teaches an article with the same coating as Applicant, the coating of Leitao must inherently induces formation of bone cells from progenitor cells. If the

coating of Applicant reacts differently in a patient's body than that of Leitao, it must be due to some limitation not present in Applicant's claim.

In regard to the limitation requiring the bond strength to be 40-65 Mpa, Examiner notes that Leitao does not specifically teach a bond strength. However, Leitao inherently has a bond strength. And it is Examiner's position that the claimed bond strength is inherent in the device of Leitao. Leitao teaches a coated implant with a coating, wherein the coating comprises a deposit of crystals nucleated directly on the implant from solution wherein said coating comprises magnesium, calcium, and phosphate ions and induces formation of bone cells. Because the same chemicals are nucleated onto the same pre-treated surface materials, the bond strength between the implants and coatings of Leitao and Applicant will inherently be the same. If Leitao's bond differs from that of Applicant's it must be due to some limitation not present in Applicant's claims.

Regarding claims 29-31 and 41-43, Leitao teaches pre-treatment of the substrate, prior to coating of said implant, using a chemical surface treatment, such as treatment with a strong mineral acid, or a mechanical surface treatment, such as sanding or scoring (col. 2, lines 40-50).

Regarding claims 28 and 40, the substrate of Leitao's invention may be made of metal, such as titanium, synthetic polymers, or ceramics (col. 2, lines 1-7).

Regarding claims 33 and 37-39, Leitao teaches a coating composition of "OCP" (table 2), which is octacalcium phosphate.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 34-35 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leitao.

Leitao teaches that which is disclosed above. Additionally, Leitao teaches that the calcium phosphate coating of his invention is preferably 1-50 microns in thickness (col. 2, line 19), overlapping the ranges set forth by the Applicant. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Leitao's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

5. Claims 27-28 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li.

Regarding claims 27-28, 32, and 36, Li teaches a coated implant wherein the coating comprises calcium ions, phosphate ions, magnesium ions, and carbonate ions (abstract and claims). The implant substrate may be metal, ceramic, or polymer (col. 4, lines 59).

Because Li teaches an article with the same coating as Applicant, the coating of Li must inherently induces formation of bone cells from progenitor cells. If the coating of Applicant reacts differently in a patient's body than that of Li, it must be due to some limitation not present in Applicant's claim.

Additionally, Li teaches that the adhesion strength of the coating to be in excess of 30MPa (col. 6, line 45). The range "in excess of 30 MPa" overlaps the range claimed by Applicant. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Li's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

In specific regard to the claim limitation of claim 36 requiring a second coating comprising calcium and phosphate ions over a first coating comprising calcium, phosphate, and magnesium ions, Examiner notes that the second coating is inclusive of an additional layer of the first coating. In this case, claim 36 differs from Li only in requiring two layers containing calcium and phosphate while Li only teaches one layer. It is well-settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 124 USPQ 378 (CCPA 1960). Additionally, depending on the thickness selected by Li, one layer containing calcium, phosphate, and magnesium would be indistinguishable from two, thinner layers of the identical chemicals.

Regarding claim 33, Li teaches the use of carbonated calcium phosphate (claim 1).

Regarding claims 34-35, Li teaches a coating thickness of 0.005 to 50 microns (claim 2), overlapping the range claimed by Applicant.

Response to Arguments

6. Applicant's arguments filed 4/10/2003 have been fully considered but they are not persuasive.

Applicant argues that Leitao does not teach the required bond strength, especially in light of the Kokubo reference.

It is Examiner's position that the bond strength of Leitao is inherently within the range claimed by Applicant. Leitao teaches a coated implant with a coating, wherein the coating comprises a deposit of octacalcium phosphate crystals nucleated directly on the implant from solution wherein said coating comprises magnesium, calcium, and phosphate ions and induces formation of bone cells. Because the same chemicals are nucleated onto the same pre-treated surface materials, the bond strength between the implants and coatings of Leitao and Applicant will inherently be the same. Since every other limitation of Applicant's is met by Leitao, then an intrinsic property, such as bond strength, must also be met. If Leitao's bond differs from that of Applicant's it must be due to some limitation not present in Applicant's claims. Regarding Kokubo, Examiner has withdrawn this rejection because the Kokubo reference did not meet all of the limitations of the claims. Therefore Kokubo could not inherently teach the same bond strength as Applicant or as Leitao. The different implant, made by a very different

process, as taught by Kokubo can not be used to determine inherent properties of Leitao, just as Kokubo was not accurate in predicting Applicant's own bond strength.

Applicant argued that no reference had been provided to teach that the bond strength of Leitao is inherently within the range of Applicant's. In response, Examiner cited Applicant's own specification as an inherency teaching. Now, however, Applicant argues that Examiner may not modify Leitao using Applicant's disclosure to render the claimed invention obvious.

Examiner merely cited Applicant's own specification to show that the coated implant of Leitao with a coating of octacalcium phosphate crystals nucleated directly on the implant from solution to induce formation of bone cells must have a bond strength of 40-65 MPa. Because Leitao teaches all of the product limitations required by the claims, Leitao's product must also have the same bond strength. If it does not, then the bond strength differs due to some limitation not required by Applicant's claims.

Examiner in no way "modified" Leitao's reference. Nor was Applicant's disclosure used in rendering the invention obvious. Examiner has made an anticipatory rejection based on inherency, not an obviousness rejection. Leitao teaches each and every element of Applicant's claims, as written. Therefore, the bond strength is inherent.

Applicant argues that Li's adhesive bond strength of greater than 30 MPa is merely speculation.

Examiner must take the teachings of Li at face value. Since Li teaches a bond strength of greater than 30 MPa, Examiner is not permitted to interpret the reference in a manner that is contradictory to that teaching.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
May 5, 2003